

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS
CORPORATION

CIVIL ACTION NO. 99-20593

2:16 MD 1203

Bartle, C.J.

February 7, 2011

Monica L. Krause ("Ms. Krause" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Alan B. Krause, Ms. Krause's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Robert J. Notske, M.D., F.A.C.C., F.A.C.P. Dr. Notske is no stranger to this litigation. According to the Trust, he has signed in excess of 45 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated August 26, 2002, Dr. Notske attested in Part II of Ms. Krause's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial

3. (...continued)

presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

dimension, and a reduced ejection fraction in the range of 50% to 60%.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$462,103.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, Darren C. Hollenbaugh, M.D., stated that claimant had "mild to moderate mitral regurgitation (moderate by Singh criteria)," which he measured at 23% to 27%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Hollenbaugh also stated that claimant's left atrial dimension measured 5.3 cm in the apical four chamber view and 3.9 cm in the parasternal long axis view. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b)ii). Finally,

4. Dr. Notske also attested that claimant suffered from New York Heart Association Functional Class II symptoms. This condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension and a reduced ejection fraction are each one of the complicating factors needed to qualify for a Level II claim.

Dr. Hollenbaugh stated that claimant had an estimated ejection fraction of 60%.⁶ An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b)iv).

In July, 2005, the Trust forwarded the claim for review to Alan J. Bier, M.D., one of its auditing cardiologists. In audit, Dr. Bier concluded that there was no reasonable medical basis for Dr. Notske's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In particular, Dr. Bier observed that:

There is a definite jet of mitral regurgitation, but it is mild. The frames that were traced on the tape were not representative of the jet and were the "worst case scenario". They were also overtraced and included substantial areas of subthreshold velocity.

Dr. Bier also concluded that there was no reasonable medical basis for Dr. Notske's finding that claimant had an abnormal left atrial dimension. Dr. Bier explained that:

The left atrium is at the upper limit of normal in size. It was 3.9 in the [antero-posterior] projection, I agree with the attesting physician there. In the apical 4-chamber view, they measure it beyond the mitral annular plane. Despite this, they get an upper limit of normal number, 5.3, so it is not enlarged. I measure it at 5.1.

Finally, Dr. Bier concluded that there was no reasonable medical basis for Dr. Notske's finding that claimant had a reduced

6. Dr. Hollenbaugh also stated that claimant's M-Mode/2d ejection fraction was 58%.

ejection fraction in the range of 50% to 60% because "[t]he left ventricle is vigorous and symmetrical in all views. Clearly more than 60%."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Krause's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷ In contest, claimant submitted declarations from Dr. Notske and Dr. Hollenbaugh. Dr. Notske stated that he reviewed claimant's echocardiogram and determined she had moderate mitral regurgitation. Specifically, Dr. Notske explained that the auditing cardiologist erred because he used a representative rather than maximum jet in violation of the Feigenbaum criteria, incorrectly determined that the echocardiographer overtraced claimant's mitral regurgitant jet, and visually estimated rather than measured the severity of claimant's mitral regurgitation. Dr. Notske also confirmed that claimant had an abnormal left atrial dimension. Further, Dr. Notske noted that, based on his observation, claimant's ejection fraction was between 55% and 60%. Finally, Dr. Hollenbaugh, who claimant noted participated in the Trust's

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Krause's claim.

Screening Program,⁸ agreed with Dr. Notske that claimant had moderate mitral regurgitation and a reduced ejection fraction of 60%.⁹

The Trust then issued a final post-audit determination, again denying Ms. Krause's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Krause's claim should be paid. On January 12, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5940 (Jan. 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 5, 2006, and claimant submitted a sur-reply on June 1, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹⁰ to review claims after the Trust and claimant have had

8. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

9. Dr. Hollenbaugh did not discuss claimant's left atrial dimension.

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through (continued...)

the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and either an abnormal left atrial dimension or a reduced ejection fraction in the range of 50% to 60%. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

10. (...continued)
the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Krause primarily reasserts the arguments made in contest, and further argues that Dr. Notske and Dr. Hollenbaugh did not include "backflow" in their measurements, instead measuring only the "true regurgitant jet." In support of this argument, claimant submitted a supplemental declaration from Dr. Notske, who referenced the Weyman and Feigenbaum texts and explained that:

The regurgitant jet that I observed was a mosaic of colors reflecting a high velocity jet, not "backflow." Backflow "does not reach velocities usually associated with regurgitant jets." Weyman, at 431.

* * *

To determine the severity of the regurgitant jet, Professor Feigenbaum instructs that "[w]ith regard to transthoracic echoes, the interpreting cardiologist should take into account the entire regurgitant jet, including the surrounding lower flow spray." Feigenbaum, at 253. Professor Weyman similarly says that the maximal jet area in any frame should be planimetered, when quantifying mitral regurgitation. Weyman, at 435.

Claimant also contends that the disagreement between the auditing cardiologist and Dr. Notske regarding the measurement of her left atrial dimension "boils down" to a difference of three millimeters, which is not enough to support a finding of no reasonable medical basis. Finally, claimant argues that the auditing cardiologist's finding regarding claimant's ejection fraction does not undermine Dr. Notske's attestation that claimant had a reduced ejection fraction because "qualitative

measurement by the auditing cardiologist is subjective and prone to errors."

In response, the Trust argues that claimant's contest does not establish a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because Dr. Notske and Dr. Hollenbaugh: (1) "relied on a short-lived jet comprised of early-systolic closing volume - backflow"; and (2) "failed to identify any sustained mitral regurgitant jet which is seen in consecutive frames throughout systole and multiple loops which meets the 20% threshold." (Emphasis in original.) The Trust also asserts that claimant's contest does not establish a reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension because: (1) claimant has "conceded that her left atrial dimension is not enlarged in the parasternal long-axis view"; (2) the sonographer measured beyond the mitral annular plane, which inflated the measurement of the left atrial dimension; (3) a difference of only three millimeters between Dr. Bier's measurement of 51 mm and Dr. Notske's measurement of 54 mm does not satisfy the requirements of the Settlement Agreement; and (4) Dr. Hollenbaugh's measurements of 39 mm in the parasternal long-axis view and 53 mm in the apical four-chamber view, as noted on claimant's echocardiogram, do not meet the requirements under the Settlement Agreement. Further, the Trust contends that claimant's contest does not establish a reasonable medical basis for the attesting physician's finding of a reduced ejection

fraction in the range of 50% to 60%. It maintains that Dr. Notske merely restates his assertion that claimant's ejection fraction is between 50% and 60% and Dr. Hollenbaugh stated on Ms. Krause's original echocardiogram report that claimant's ejection fraction was normal. Finally, the Trust argues that: (1) Dr. Hollenbaugh's participation in the Trust Screening Program does not transform "him into an agent of the Trust or conclusively [establish] that there is a reasonable medical basis for his findings"; (2) the auditing cardiologist is not required to provide exact measurements and that the court has accepted the practice of "eyeballing" the regurgitant jet; and (3) neither the Settlement Agreement nor the Audit Rules requires the auditing cardiologist to provide citations to the provisions that the attesting physician violated.

In her sur-reply, claimant argues that Weyman allows for the maximum regurgitant jet to be measured at any point during systole, including in early systole. Ms. Krause also claims that the auditing cardiologist "found the presence of a regurgitant jet, which is by definition not backflow," and only the Trust argues the presence of backflow.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Vigilante observed mild to moderate mitral regurgitation, explaining that:

The RJA/LAA ratio in the apical 2-chamber view was less than 10%. The mitral regurgitation jet was most impressive in the apical 4-chamber view. This was still a narrow posterolaterally directed jet that was noted to stop about 2/3 along the lateral left atrial wall. The RJA was no greater than 3.5 cm² in its largest area. The left atrial area was greater than 23 cm². The LAA was accurately determined in the still frame which the sonographer has used to measure the left atrial dimension in the apical 4-chamber view. Therefore, the RJA/LAA ratio was no greater than 15%. Indeed, other cardiac cycles were measured and the RJA/LAA was less than 15% in all of these cardiac cycles. The RJA/LAA ratio does not come close to 20% and it would not be reasonable to conclude that moderate mitral regurgitation was present on this study. In addition, the sonographer documented two RJA's and two LAA's. The calculations of this individual's measurements result in the inaccurate ratio of 23 to 27% that was noted on the formal echocardiogram report signed by Dr. Hollenbaugh. However, the two RJA measurements are completely inaccurate as they both include non-mitral regurgitant low velocity flow. Also, the LAA measurements were completely inaccurate as they were performed on an off axis view of the left atrium and not in the view where the left atrium appeared the largest as previously mentioned.

* * *

... An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.

Dr. Vigilante also found no reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension, stating, in relevant part, that:

The largest left atrium dimension in the parasternal long-axis view was 3.9 cm. As this was a good quality study, the left

atrium could be measured accurately at 3.9 cm and could not be reasonably read as greater than 4.0 cm, even allowing for inter-reader variability. The largest measurement in the apical 4-chamber view was 5.31 cm. A still frame image was documented by the sonographer and this individual's measurement of the left atrium in this frame in the apical 4-chamber view was 5.31 cm. This was an inaccurate measurement. The distal point was past the posterior wall of the left atrium. My accurate measurement of the left atrium in this view (which was the view in which the left atrium appeared the largest) was 5.1 cm.

Finally, Dr. Vigilante found no reasonable medical basis for attesting physician's finding of a reduced ejection fraction in the range of 50% to 60%, explaining that "[t]he left ventricle is normal in size with vigorous contractility and the left ventricular ejection fraction was calculated at 65%."

In response to the Technical Advisor Report, claimant argues that: (1) the Technical Advisor found that the "August 26, 2002 echocardiogram reflected true mitral regurgitation, as distinguished from 'backflow,'" and, thus, Dr. Notske and Dr. Hollenbaugh complied with PTO No. 2640, which instructs a cardiologist to "distinguish true regurgitation from artifacts, phantom jets and backflow" PTO No. 2640 at 12 (Nov. 14, 2002); (2) the Technical Advisor failed to include lower flow spray in measuring the mitral regurgitant jet and, thus, did not comply with Feigenbaum; (3) the Technical Advisor substituted his own opinion for those of Dr. Notske and Dr. Hollenbaugh; (4) the Technical Advisor "ignores [the] fact that [Dr. Hollenbaugh] measured the ejection fraction by the

universally accepted M Mode method which measured the ejection fraction at 58%" while the Technical Advisor did not state how he measured the ejection fraction; and (5) the Technical Advisor "failed to show that the 'off-axis' view [of the left atrium] rendered the interpretation of [Dr. Notske and Dr. Hollenbaugh] without a reasonable medical basis."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant did not adequately challenge the auditing cardiologist's finding that the measurements of mitral regurgitation were "overtraced and included substantial areas of subthreshold velocity." Dr. Bier also found that claimant's left atrial dimension was measured "beyond the mitral annular plane" and that claimant's ejection fraction was "[c]learly more than 60%" as her "left ventricle [was] vigorous and symmetrical in all views." Claimant did not identify any particular error in these specific findings. Mere disagreement with the auditing cardiologist is insufficient to meet a claimant's burden of proof.

We also disagree that the opinions of Dr. Notske and Dr. Hollenbaugh establish a reasonable medical basis for finding moderate mitral regurgitation. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole;

(4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, both Dr. Bier and Dr. Vigilante determined that claimant had mild mitral regurgitation. Specifically, Dr. Bier determined that the measurements on claimant's echocardiogram were "overtraced and included substantial areas of subthreshold velocity."

Dr. Vigilante observed that "the two RJA measurements are completely inaccurate as they both include non-mitral regurgitant low velocity flow." Dr. Vigilante also concluded that "the LAA measurements were completely inaccurate as they were performed on an off axis view of the left atrium and not in the view where the left atrium appeared the largest as previously mentioned."¹¹

Such unacceptable practices cannot provide reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

In addition, we reject claimant's argument that Dr. Bier did not apply the appropriate standard in evaluating Ms. Krause's echocardiogram. Specifically, Dr. Bier concluded that "[t]he frames that were traced on the tape were not

11. For this reason as well, we disagree with claimant that Dr. Vigilante "substituted" his opinion for those of Dr. Notske and Dr. Hollenbaugh.

representative of the jet and were the 'worst case scenario.'" Although claimant objects to Dr. Bier's use of "representative" beats to evaluate the level of mitral regurgitation, we have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram." PTO No. 6997 at 11 (Feb. 26, 2007). "To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." Id.

Similarly, we disagree that there is a reasonable medical basis for Dr. Notske's representation that claimant had an abnormal left atrial dimension simply because there is a difference of only 3 millimeters in the measurements of claimant's left atrial supero-inferior dimension. The Settlement Agreement specifically defines an abnormal left atrial supero-inferior systolic dimension as greater than 5.3 cm in the apical four chamber view. See Settlement Agreement § IV.B.2.c.(2)(b)ii).¹² Dr. Bier and Dr. Vigilante determined that claimant's left atrial supero-inferior systolic dimension

12. The Settlement Agreement also defines an abnormal left atrial antero-posterior systolic dimension as greater than 4.0 cm in the parasternal long axis view. See id. As claimant does not adequately contest the determinations of the reviewing cardiologist, the auditing cardiologist, and the Technical Advisor that her left atrial antero-posterior systolic dimension was 3.9 cm, this cannot serve as a basis for her claim.

was only 5.1 cm in the apical four chamber view. Dr. Bier explained that the echocardiographer measured claimant's left atrial supero-inferior systolic dimension "beyond the mitral annular plane." Dr. Vigilante also concluded that this measurement was "inaccurate" because "[t]he distal point was past the posterior wall of the left atrium." Moreover, Dr. Vigilante specifically determined that "[a]n echocardiographer could not reasonably conclude that an abnormal left atrial systolic dimension was present on this study even taking into account inter-reader variability." Adopting claimant's argument would allow a claimant to recover Matrix Benefits when his or her left atrial supero-inferior systolic dimension was less than 5.3 cm in the apical four chamber view. This result would render meaningless the standards established in the Settlement Agreement.

Further, we reject claimant's assertion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of her claim was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and
those Diet Drug Recipients in Subclass 1(b)
who have been diagnosed by a Qualified
Physician as FDA Positive by an
Echocardiogram performed between the

commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit requirement for all claims for Matrix Benefits. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

Finally, we disagree with claimant's argument that the auditing cardiologist inappropriately relied on visual estimation. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate

mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See PTO No. 2640 at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision, and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO 2640.¹³

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation and either an abnormal left atrial dimension or a reduced ejection fraction in the range of 50% to 60%. Therefore, we will affirm the Trust's denial of Ms. Krause's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

13. In any event, the Technical Advisor, although not required, made specific measurements of claimant's level of mitral regurgitation, which further establish that she is not entitled to Matrix Benefits.